UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

| APPLICATION NO. | | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | • | |
|-------------------|------------------------|--------------------------------------|----------------------|---------------------|------------------|---|--|
| | 10/528,509 03/18/2005 | | Akikuni Yagita | 3190-077 | 4380 | | |
| | | 7590 06/27/2007· WERSOX, P.L.L.C. | | EXAMINER | | | |
| 400 HOLIDAY COURT | | | | · GODDARD, LAURA B | | | |
| | SUITE 102 WARRENTON | J. VA 20186 | | ART UNIT | PAPER NUMBER | | |
| | | | | 1642 | · | • | |
| | | | • | | · | | |
| | | | · · | MAIL DATE | DELIVERY MODE | | |
| | | | | 06/27/2007 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| 1000 | | Application No. | T | Applicant(s) | | | | | |
|---|--|--|--|---|--|--|--|--|--|
| Office Action Summary | | 10/528,509 | | YAGITA, AKIKUNI | | | | | |
| | | Examiner | | Art Unit | | | | | |
| | | Laura B. Goddard, F | Ph D | 1642 | | | | | |
| | PATE of this communication app | | | | | | | | |
| Period for Reply | | | | | | | | | |
| WHICHEVER IS LON - Extensions of time may be a after SIX (6) MONTHS from - If NO period for reply is spec - Failure to reply within the se | TUTORY PERIOD FOR REPLY IGER, FROM THE MAILING DA available under the provisions of 37 CFR 1.13 the mailing date of this communication. Cified above, the maximum statutory period with or extended period for reply will, by statute, ffice later than three months after the mailing ent. See 37 CFR 1.704(b). | ATE OF THIS COMI 36(a). In no event, however vill apply and will expire SIX cause the application to be | MUNICATION r, may a reply be time (6) MONTHS from the come ABANDONED | l. ely filed the mailing date of this communication. O (35 U.S.C. § 133). | | | | | |
| Status | | | | | | | | | |
| 1) Responsive to o | communication(s) filed on 18 Ma | <u>arch 2005</u> . | | | | | | | |
| 2a) ☐ This action is Fi | 2a) This action is FINAL . 2b) This action is non-final. | | | | | | | | |
| | cation is in condition for allowar | * | · · · · · · · · · · · · · · · · · · · | | | | | | |
| closed in accord | dance with the practice under E | x parte Quayle, 193 | 35 C.D. 11, 45 | 3 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | | | | |
| 4)⊠ Claim(s) <u>1-20</u> is | s/are pending in the application. | | | | | | | | |
| · | e claim(s) is/are withdrav | vn from consideration | on. | | | | | | |
| 5) Claim(s) | | | | | | | | | |
| 6) Claim(s) | • | | | | | | | | |
| 7) ☐ Claim(s) 8) ☑ Claim(s) 1-20 a | re subject to restriction and/or e | election requiremen | nt | | | | | | |
| 0) <u>23</u> | ind dubject to realination and a | sicolioni roquii cimon | •• | | | | | | |
| Application Papers | | | | | | | | | |
| · · | n is objected to by the Examine | | | | | | | | |
| - · · | 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| | | - | | | | | | | |
| <u> </u> | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| , — | | | | | | | | | |
| Priority under 35 U.S.C. | | | | | | | | | |
| | nt is made of a claim for foreign | priority under 35 U | .S.C. § 119(a) | -(d) or (f). | | | | | |
| · ·- | a) All b) Some * c) None of: | | | | | | | | |
| Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No | | | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | | | |
| * See the attached | * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| Attachment(s) | | | | | | | | | |
| 1) Notice of References Cit | | | terview Summary | | | | | | |
| 2) Notice of Draftsperson's3) Information Disclosure S | Patent Drawing Review (PTO-948) tatement(s) (PTO/SB/08) | | aper No(s)/Mail Da otice of Informal P | | | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | | | | |

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13 and 15-20, drawn to the special technical feature of a therapeutic agent for cancer, wherein a tyrosine kinase inhibitor and an IL-12 inducer are used in combination.

Group II, claim(s) 14, drawn to the special technical feature of a therapeutic method for cancer comprising administering the therapeutic agent for cancer according to claim 1.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking Groups I and II appears to be a combination of a tyrosine kinase inhibitor and an IL-12 inducer.

However, said technical feature does <u>not</u> constitute a special technical feature in view Shapira et al (J of Immunology, 1994, 153:1818-1824) as evidenced by Yun et al

(Infection and Immunity, 2002, 70:5695-5705). Shapira et al teach a combination of tyrosine kinase inhibitors herbimycin A or genistein with lipopolysaccharide (LPS) isolated from *P. gingivalis* (p. 1819, both columns; p. 1820, col. 1; Figure 1; p. 1821, col. 1; Figure 4 and 6).

As evidenced by Yun et al, LPS isolated from *P. gingivalis* is an inducer of IL-12 (abstract; p. 5696, col. 1; Figure 3).

Therefore, the technical feature linking the inventions of Groups I and II does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly, Groups I and II are not so linked by the same or a corresponding special technical feature as to form a single general incentive concept and restriction for examination purposes as indicated is proper.

SPECIES ELECTION

Species Election for Groups I and II

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The receptor species are as follows (claim 2):

- (1) HER2/neu,
- (2) HER3,
- (3) HER4,

Application/Control Number: 10/528,509 Page 4

Art Unit: 1642

(4) c-kit,

(5) PDGFR,

(6) bcr-abl, or

(7) EGFR.

The following claim(s) are generic: 1 and 14.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each receptor is functionally and structurally distinct and requires a functionally and structurally distinct inhibitor.

Additional Species Election for Group I

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The combination substance species are as follows:

(1) chemotherapeutic agent and radiation therapy (claim 6),

(2) substance that selectively acts on NKR-P1 of NKT cell (claims 7, 17, and 18),

or

(3) substance having neovascularization inhibiting capabilities (claim 8).

The following claim(s) are generic: 1, 2, and 3.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each additional substance is functionally and structurally distinct.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/528,509 Page 7

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN UNGAR, PH.D PRIMARY EXAMINER

> Laura B Goddard, Ph.D. Examiner Art Unit 1642